REMARKS

The Office Action dated December 12, 2003 had been read and carefully considered and the present amendment presented to better define the subject invention.

In that Office Action, an objection was made to the claim numbering and Applicant's attorney apologizes for the inadvertent mis-numbering, however, it is believed that the numbering has been corrected herein and that the numbering is now consecutive in accordance with 37 CFR 1.126. Claims 1, 13, 19 and 27 were also objected to because of certain informalities and, again it is submitted that such informalities have been cleared up with the present amendment.

Claim 14 and 15 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite and claim 14 has thus been amended herein to clarify the claim language and to remove the indefiniteness.

Claims 1-5 were rejected under 35 U.S.C. 102(b) as being anticipated by Ritchart *et al*, U.S. Patent 5,649,547. Claims 1-4 were similarly rejected under Section 102(b) as being anticipated by Yoon, U.S. Patent 6,059,734.

Claims 1-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over Follmer et al, U.S. patent 6,447,525. Claims 1-8 were rejected under Section 103(a) as being unpatentable over Krag, U.S. Patent 6,363,940. Claims 13 and 16-21 were rejected under Section 103(a) as being unpatentable over Yoon, in view of Marini, U.S. Patent 6,077,290.

Claims 27-20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wang, U.S. Patent 5,320,110 in view of Ritchart *et al.* Finally, claims 27 and 32 were rejected under Section 103(a) as being unpatentable over Wang in view of Follmer *et al.*

Claims 10-12, 22-26, 31 and 33 were objected to as being dependent upon a rejected base claim but were indicated as being allowable if rewritten in independent form to include

the limitations of the base claim and any intervening claims. Claims 14 and 15 were also indicated as being allowable under the same conditions if also rewritten to overcome the Section 112, second paragraph, rejection. The indication of allowable subject matter is gratefully appreciated.

Accordingly, the independent claims have all been amended to better define the present invention. In particular, claim 1 as been amended to make clear that the distal end is a closed end and that the at least one opening is a peripheral opening, that is, in the side of the outer tube proximate to the closed, distal end. In addition, consistent with the unique intended use of the present invention, it is further recited, that the at least one articulating member has an "operative surface" that faces the proximal end of the biopsy needle when the at least one articulating member is in its extended position and that such operative surface contacts the pleural cavity of the patient to obtain the tissue sample.

The claims have also been amended to provide an alternative term to describe the "inner tube" and is now referred to as an "inner movable member" since, as suggested by the Examiner with respect to the Follmer *et al* reference, the "tube" as was shown in the present application is a solid rod, as evidenced by the drawings where the element 24 is clearly shown to be a solid tube and not hollow. Thus, the description in the specification and the clear import of the drawings show that the element called the inner tube is a solid member and thus the term "inner movable member" would appear to be a better alternative description of that element of the biopsy needle since the inner movable member can, of course, be hollow or solid.

The amendments are submitted as fully overcoming the Section 102(b) rejections based upon Ritchart *et al* and Yoon and the amended claim 1 better describes the actual use of Applicant's biopsy needle for obtaining a sample of tissue from a rather particular location within the patient, that is, from the parietal pleura of the patient. Neither Ritchart *et al* nor Yoon are usable for that purpose.

To summarize the present invention, and its unique use, the device is intended to

obtain a tissue sample from the parietal pleura of a patient and which surface is the inside layer of the rib cage within the pleural cavity. Thus, the surface where the sample is to be removed basically faces inwardly of the patient, toward the lungs and, therefore, for an instrument to successfully obtain a sample of the tissue, the device must enter the pleural cavity and then be positionable so as to contact the inside surface facing inwardly such that the operative surface from which the sample is removed must face outwardly with respect to the patient, that is, toward the proximal end of the biopsy needle that remains, of course, exterior of the patient.

In such manner, the operative surface or surfaces of the articulating members extend outwardly from the biopsy needle but also face the exterior of the patient or towards the proximal end of the biopsy needle lying external of the patient so that the sample tissue can be obtained from the interior pleural surface that faces inwardly toward the lungs of the patient. The location of the sample area creates unique problems not faced nor solved by any of the primary cited prior art references.

As can be seen, therefore, the Ritchart *et al* device has an opening, in the Fig. 29 embodiment cited, in the distal end and coaxially with the main longitudinal axis of the device and could not be used to obtain a sample of tissue from a surface such as the pleural cavity that is basically behind the distal end of the Ritchart *et al* device and which must have its distal end open in order to be operable. It is, therefore, submitted that the totally different use and function of the subject invention that is now better reflected in independent claim 1 distinguishes that invention over the Ritchart *et al* reference. There are also, no operative surfaces facing outwardly toward the proximal end of the Ritchart *et al* device nor, due to the different use, would there be any reason to have operative surface so oriented with the Ritchart *et al* reference.

The same is true of the Toon reference where, again, the device has an opening in the distal end along the longitudinal axis of the device through which the arms 287 extend and those arms do not have operative surfaces that face the proximal end of the device for collecting a sample of tissue that faces internal of the patient and there is no opening in the periphery of the device. As can readily be seen, therefore, the Toon device cannot be used to

obtain a sample of tissue from the internal surface of the pleural cavity and, as now amended, it is submitted that claim 1 clearly points out and recites the distinctions between the Toon device and the biopsy needle of the present invention in its operation and function.

Taking next, the rejection under 35 U.S.C. 103(a) of claim 1 based upon Follmer *et al*, the device of Follmer *et al* is a flexible catheter intend to remove material from a body lumen such as a coronary or other artery. It has a length ranging from about 50 to 200 cm for introduction into that particular lumen of the patient. The device is not a biopsy needle nor could it ever be used in the removal of tissue from the pleural cavity of a patient and there is no operative surface of an articulating member that could face the proximal end of the device in order to contact the pleural cavity of a patient to obtain tissue samples therefrom. It is submitted that the newly amended claim 1 is patentable over this reference.

Next, with the Krag reference, there are no articulate members having operative surfaces since there are only anchors 310 used to hold the device in place so that a cutter 200 can remove a relatively large volume of tissue from the patient. There would seem to be no such operative surfaces on the anchors 310 and no reason to have any operative surfaces to remove tissue samples since the use of the Krag instrument is far afield from the use and function of Applicant's biopsy needle used to obtain tissue samples from the pleural cavity.

Taking the rejection of the next independent claim, claim 13, the rejection is based upon 35 U.S.C. 103(a) as unpatentable over Yoon in view of Marini. As now amended, however, claim 13 has the same limitations inserted therein as were incorporated into claim 1 and, therefore, the same arguments apply with respect to the presence of a closed distal end, the at least one peripheral opening formed in the outer tube and the presence of at least one articulating member that has an operative surface facing the proximal end of the biopsy needle when the at least one articulating member is in its extended position.

As explained, Yoon does not have those features and since Yoon operates on an entirely different principle and for a different purpose, there would be no way or reason to modify Yoon by resort to Marini in order to be relevant to claim 13.

Taking, then the rejection of Claim 27, the independent method claim, the claim language now includes the presence of a needle having a closed distal end such that the at least one articulating member extends outwardly from the needle proximate to the closed distal end. That device is not disclosed in Wang and there is nothing in Ritchart *et al*, as explained, that would enable one to modify Wang to enable one to remove a sample of tissue from a pleural cavity since Ritchart *et al* has the operative component extending out the distal end and which would not provide any logical modification to Wang, far less result in a device that could be used to obtain a sample of tissue from a pleural cavity to collect a sample of the pleura.

The same is true in the use of Follmer *et al* to modify Wang. The method of the present invention is directed to the removal of tissue from a pleural cavity and not a variety of body lumens, to which the Follmer *et al* reference is directed and it simply would not be logical or reasonable to modify Wang, if indeed that were even possible, with any of the teachings of Follmer *et al* to construct a biopsy needle that can carry out the method of claim 27 considering the particular location and orientation of the pleural cavity.

Accordingly it is submitted that, as now amended, the claim of the present application are in allowable form and an allowance of the present application is respectfully solicited.

Respectfully submitted

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